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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550,173	04/14/2000	Norihisa Ooc	2185-0424-SP	8838

7590 03/11/2002

Birch Stewart Kolasch & Birch LLP  
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EXAMINER

DAVIS, KATHARINE F

ART UNIT	PAPER NUMBER
1636	13

DATE MAILED: 03/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/550,173	OOE ET AL.	
	Examiner	Art Unit	
	Katharine F. Davis	1636	

*The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

A SHORTENED STATUTORY PERIOD FOR REPETING THE MAILING DATE OF THIS COMMUNICATION.

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

- If FAILURE to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 25 February 2002.

2a)  This action is **FINAL**.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### **Disposition of Claims**

4)  Claim(s) 1-9 and 11-18 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 9 is/are allowed.

6)  Claim(s) 1-3,5-8,11-15,17 and 18 is/are rejected.

7)  Claim(s) 4 and 16 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 14 April 2000 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 25, 2002 has been entered. New claims 17 and 18 were added. Claims 1-9 and 11-18 are pending in the instant application.

The rejection of claim 16 under 35 U.S.C. 103(a) as being unpatentable over Evans *et al.* (US Patent 5,298,429, IDS reference) has been withdrawn in view of the arguments presented by the Applicants in the Response filed January 25, 2002.

### ***Claim Objections***

Claims 17 and 18 are objected to because of the following informalities: Both claims appear to be missing a word "said" in line 5. This objection may be overcome by amending both claims 17 and 18 to recite "...wherein **said** transcription...in line 5.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the phrase "...at least one inert nucleotide..." in part (a), line 9. It is unclear what part of the transcription control region the inert nucleotide is part of, the promoter or the recognition sequence.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-8, 11-15 and 17 remain rejected under 35 U.S.C. 102(b) as being anticipated by Evans *et al.* (US Patent 5,298,429: IDS reference). This rejection is maintained for reasons made of record in the previous Office Action mailed on January 3, 2001 and in the Final Rejection mailed on September 25, 2001. Evans *et al.* teaches a mammalian cell containing non-endogenous DNA which expresses a hormone receptor (said receptor can be an intranuclear hormone receptor, estrogen receptor, androgen receptor and/or a thyroid hormone receptor) and a

DNA sequence which expresses a hormone response element operatively linked to a reporter gene sequence. The test cell of Evans *et al.* is made by introducing into said cell plasmids which contain the non-endogenous DNA sequences and selection marker gene sequences for propagation of the plasmids in the test cells. The non-endogenous DNA sequences are eukaryotic sequences which are known in the art to have TATA box promoter sequences. The test cells are employed in a method for determining whether a substance is a hormone receptor agonist or a hormone receptor antagonist. The test cells are cultured in the presence of the substance and the expression of the reporter gene is monitored to assess transcription activity. The test cells with reagents for making and using the test cells can be contained in a kit. The elements in claims 1, 2, 5-8 and 10-15 read on the test cells and bioassay of Evans *et al.* (see entire document).

Applicants' arguments presented on pages 5-7 of the Response filed on January 25, 2002 have been carefully considered but have not been found to be persuasive. Applicants argue that Evans *et al.* fails to describe or suggest a cell securely maintaining a DNA comprising in a molecule a selective marker gene and a reporter gene. However, Evans *et al.* describes an assay (see column 34) wherein the reporter gene and the selective marker gene are comprised together within a molecule. Figure II-1 illustrates this assay wherein the CAT reporter gene is located within the same plasmid molecule as the amp selective marker gene. Applicants argue further that Evans *et al.* fails to provide any specific description of the reporter gene or selective marker gene to determine the condition of the reporter gene relative to the selective marker gene. Applicants cite example II.F. (d) from Evans *et al.* (columns 42-43) wherein pMTVCAT is introduced into a CV-1 cell. According to Applicants, the disclosure of Evans *et al.* fails to

describe or suggest that the selective marker and the reporter gene are in a molecule before the introduction of pMTVCAT into the CV-1 cell and thus due to the lack of description it intuitively follows that Evans *et al.* fails to describe the pMTVCAT after the introduction into the CV-1 cell. Based on this example Applicants assert that one of ordinary skill in the art would not be able to determine the condition of the reporter gene relative to the selection marker gene in the test cell and would not be convinced that the selective marker gene and the reporter gene are together in a molecule as is required in the instant invention. However as is shown by the assay described in Figure 11-1 Evans *et al.* does disclose that a reporter gene and a selective marker gene can be present within the same molecule (plasmid). Additionally the reporter plasmids used in the bioassays described by Evans *et al.* (column 18, lines 16-20) carry a selectable marker gene such as amp. Thus one of skill in the art would be convinced that the reporter gene and the selective marker gene are together in a molecule.

For the reasons above and the reasons made of record in the previous Office Action mailed on January 3, 2001 and in the Final Rejection mailed on September 25, 2001, the rejection of claims 1-3, 5-8, 11-15 and 17 under 35 U.S.C. 102(b) is maintained.

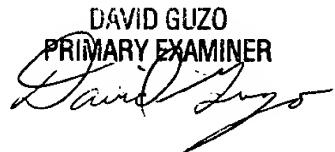
### ***Conclusion***

Claim 9 is allowable. Claims 1-3, 5-8, 11-15, 17 and 18 are rejected. Claims 4 and 16 are objected to as being dependent upon rejected base claims but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195 with direct desktop RightFax (703) 746-5199. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications. Any inquiry of a general nature or any inquiry concerning the formalities of this application should be directed to Patent Analyst Tracey Johnson whose telephone number is (703) 305-2982.

Katharine F. Davis  
March 9, 2002

DAVID GUZO  
PRIMARY EXAMINER  


## Search History

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<u>L10</u>	reporter same ligand	1732	<u>L10</u>	
<u>L9</u>	L8 same reporter	4	<u>L9</u>	
<u>L8</u>	l4 same androgen	45	<u>L8</u>	
<u>L7</u>	L6 same reporter	19	<u>L7</u>	
<u>L6</u>	L4 same estrogen	135	<u>L6</u>	
<u>L5</u>	L4 same intranuclear	3	<u>L5</u>	
<u>L4</u>	agonist\$ same (screen\$ or assa\$)	9061	<u>L4</u>	
<u>L3</u>	L1 and reporter	20	<u>L3</u>	
<u>L2</u>	L1 same reporter	0	<u>L2</u>	
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